

TITLE 42--PUBLIC HEALTH

CHAPTER I--PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 8--CERTIFICATION OF OPIOID TREATMENT PROGRAMS--Table of Contents

Subpart A--Accreditation

Sec. 8.1 Scope.

The regulations in this part establish the procedures by which the Secretary of Health and Human Services (the Secretary) will determine whether a practitioner is qualified under section 303(g) of the Controlled Substances Act (21 U.S.C. 823(g)) to dispense opioid drugs in the treatment of opioid addiction. These regulations also establish the Secretary's standards regarding the appropriate quantities of opioid drugs that may be provided for unsupervised use by individuals undergoing such treatment (21 U.S.C. 823(g)(1)). Under these regulations, a practitioner who intends to dispense opioid drugs in the treatment of opioid addiction must first obtain from the Secretary or by delegation, from the Administrator, Substance Abuse and Mental Health Services Administration (SAMHSA), a certification that the practitioner is qualified under the Secretary's standards and will comply with such standards. Eligibility for certification will depend upon the practitioner obtaining accreditation from an accreditation body that has been approved by SAMHSA. These regulations establish the procedures whereby an entity can apply to become an approved accreditation body. This part also establishes requirements and general standards for accreditation bodies to ensure that practitioners are consistently evaluated for compliance with the Secretary's standards for opiate addiction treatment with an opioid agonist treatment medication.

Sec. 8.2 Definitions.

The following definitions apply to this part:

Accreditation means the process of review and acceptance by an accreditation body.

Accreditation body means a body that has been approved by SAMHSA under Sec. 8.3 to accredit opioid treatment programs using opioid agonist treatment medications.

Accreditation body application means the application filed with SAMHSA for purposes of obtaining approval as an accreditation body, as described in Sec. 8.3(b).

Accreditation elements mean the elements or standards that are developed and adopted by an accreditation body and approved by SAMHSA.

Accreditation survey means an onsite review and evaluation of an opioid treatment program by an accreditation body for the purpose of determining compliance with the Federal opioid treatment standards described in Sec. 8.12.

Accredited opioid treatment program means an opioid treatment program that is the subject of a current, valid accreditation from an accreditation body approved by SAMHSA under Sec. 8.3(d).

Certification means the process by which SAMHSA determines that an opioid treatment program is qualified to provide opioid treatment under the Federal opioid treatment standards.

Certification application means the application filed by an opioid treatment program for purposes of obtaining certification from SAMHSA, as described in Sec. 8.11(b).

Certified opioid treatment program means an opioid treatment program that is the subject of a current, valid certification under Sec. 8.11.

Comprehensive maintenance treatment is maintenance treatment provided in conjunction with a comprehensive range of appropriate medical and rehabilitative services.

Detoxification treatment means the dispensing of an opioid agonist treatment medication in decreasing doses to an individual to alleviate adverse physical or psychological effects incident to withdrawal from the continuous or sustained use of an opioid drug and as a method of bringing the individual to a drug-free state within such period.

Federal opioid treatment standards means the standards established by the Secretary in Sec. 8.12 that are used to determine whether an opioid treatment program is qualified to engage in opioid treatment. The Federal opioid treatment standards established in Sec. 8.12 also include the standards established by the Secretary regarding the quantities of opioid drugs which may be provided for unsupervised use.

For-cause inspection means an inspection of an opioid treatment program by the Secretary, or by an accreditation body, that may be operating in violation of Federal opioid treatment standards, may be providing substandard treatment, or may be serving as a possible source of diverted medications.

Interim maintenance treatment means maintenance treatment provided in conjunction with appropriate medical services while a patient is awaiting transfer to a program that provides comprehensive maintenance treatment.

Long-term detoxification treatment means detoxification treatment for a period more than 30 days but not in excess of 180 days.

Maintenance treatment means the dispensing of an opioid agonist treatment medication at stable dosage levels for a period in excess of 21 days in the treatment of an individual for opioid addiction.

Medical director means a physician, licensed to practice medicine in the jurisdiction in which the opioid treatment program is located, who assumes responsibility for administering all medical services performed by the program, either by performing them directly or by delegating specific responsibility to authorized program physicians and healthcare professionals functioning under the medical director's direct supervision.

Medical and rehabilitative services means services such as medical evaluations, counseling, and rehabilitative and other social programs (e.g., vocational and educational guidance, employment placement), that are intended to help patients

in opioid treatment programs become and/or remain productive members of society.

Medication unit means a facility established as part of, but geographically separate from, an opioid treatment program from which licensed private practitioners or community pharmacists dispense or administer an opioid agonist treatment medication or collect samples for drug testing or analysis.

Opiate addiction is defined as a cluster of cognitive, behavioral, and physiological symptoms in which the individual continues use of opiates despite significant opiate-induced problems. Opiate dependence is characterized by repeated self-administration that usually results in opiate tolerance, withdrawal symptoms, and compulsive drug-taking. Dependence may occur with or without the physiological symptoms of tolerance and withdrawal.

Opioid agonist treatment medication means any opioid agonist drug that is approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for use in the treatment of opiate addiction.

Opioid drug means any drug having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability.

Opioid treatment means the dispensing of an opioid agonist treatment medication, along with a comprehensive range of medical and rehabilitative services, when clinically necessary, to an individual to alleviate the adverse medical, psychological, or physical effects incident to opiate addiction. This term encompasses detoxification treatment, short-term detoxification treatment, long-term detoxification treatment, maintenance treatment, comprehensive maintenance treatment, and interim maintenance treatment.

Opioid treatment program or "OTP" means a program or practitioner engaged in opioid treatment of individuals with an opioid agonist treatment medication.

Patient means any individual who undergoes treatment in an opioid treatment program.

Program sponsor means the person named in the application for certification described in Sec. 8.11(b) as responsible for the operation of the opioid treatment program and who assumes responsibility for all its employees, including any practitioners, agents, or other persons providing medical, rehabilitative, or counseling services at the program or any of its medication units. The program sponsor need not be a licensed physician but shall employ a licensed physician for the position of medical director.

Registered opioid treatment program means an opioid treatment program that is registered under 21 U.S.C. 823(g).

Short-term detoxification treatment means detoxification treatment for a period not in excess of 30 days.

State Authority is the agency designated by the Governor or other appropriate official designated by the Governor to exercise the responsibility and authority within the State or Territory for governing the treatment of opiate addiction with an opioid drug.

Treatment plan means a plan that outlines for each patient attainable short-term treatment goals that are mutually acceptable to the patient and the opioid treatment program and which specifies the services to be provided and the frequency and schedule for their provision.

Sec. 8.3 Application for approval as an accreditation body.

(a) Eligibility. Private nonprofit organizations or State governmental entities, or political subdivisions thereof, capable of meeting the requirements of this part may apply for approval as an accreditation body.

(b) Application for initial approval. Three copies of an accreditation body application form [SMA-163] shall be submitted to SAMHSA at rm. 12-105, 5600 Fishers Lane, Rockville, MD 20857, and marked ATTENTION: OTP Certification Program. SAMHSA will consider and accept the electronic submission of these materials when electronic submission systems are developed and available. Accreditation body applications shall include the following information and supporting documentation:

(1) Name, address, and telephone number of the applicant and a responsible official for the accreditation body. The application shall be signed by the responsible official;

(2) Evidence of the nonprofit status of the applicant (i.e., of fulfilling Internal Revenue Service requirements as a nonprofit organization) if the applicant is not a State governmental entity or political subdivision;

(3) A set of the accreditation elements or standards and a detailed discussion showing how the proposed accreditation elements or standards will ensure that each OTP surveyed by the applicant is qualified to meet or is meeting each of the Federal opioid treatment standards set forth in Sec. 8.12;

(4) A detailed description of the applicant's decisionmaking process, including:

(i) Procedures for initiating and performing onsite accreditation surveys of OTPs;

(ii) Procedures for assessing OTP personnel qualifications;

(iii) Copies of an application for accreditation, guidelines, instructions, and other materials the applicant will send to OTPs during the accreditation process, including a request for a complete history of prior accreditation activities and a statement that all information and data submitted in the application for accreditation is true and accurate, and that no material fact has been omitted;

(iv) Policies and procedures for notifying OTPs and SAMHSA of deficiencies and for monitoring corrections of deficiencies by OTPs;

(v) Policies and procedures for suspending or revoking an OTP's accreditation;

(vi) Policies and procedures that will ensure processing of applications for accreditation and applications for renewal of accreditation within a timeframe approved by SAMHSA; and

(vii) A description of the applicant's appeals process to allow OTPs to contest adverse accreditation decisions.

(5) Policies and procedures established by the accreditation body to avoid conflicts of interest, or the appearance of conflicts of interest, by the applicant's board members, commissioners, professional personnel, consultants, administrative personnel, and other representatives;

(6) A description of the education, experience, and training requirements for the applicant's professional staff, accreditation survey team membership, and the identification of at least one licensed physician on the applicant's staff;

(7) A description of the applicant's training policies;

(8) Fee schedules, with supporting cost data;

(9) Satisfactory assurances that the body will comply with the requirements of Sec. 8.4, including a contingency plan for investigating complaints under Sec. 8.4(e);

(10) Policies and procedures established to protect confidential information the applicant will collect or receive in its role as an accreditation body; and

(11) Any other information SAMHSA may require.

(c) Application for renewal of approval. An accreditation body that intends to continue to serve as an accreditation body beyond its current term shall apply to SAMHSA for renewal, or notify SAMHSA of its intention not to apply for renewal, in accordance with the following procedures and schedule:

(1) At least 9 months before the date of expiration of an accreditation body's term of approval, the body shall inform SAMHSA in writing of its intent to seek renewal.

(2) SAMHSA will notify the applicant of the relevant information, materials, and supporting documentation required under paragraph (b) of this section that the applicant shall submit as part of the renewal procedure.

(3) At least 3 months before the date of expiration of the accreditation body's term of approval, the applicant shall furnish to SAMHSA three copies of a renewal application containing the information, materials, and supporting documentation requested by SAMHSA under paragraph (c)(2) of this section.

(4) An accreditation body that does not intend to renew its approval shall so notify SAMHSA at least 9 months before the expiration of the body's term of approval.

(d) Rulings on applications for initial approval or renewal of approval.

(1) SAMHSA will grant an application for initial approval or an application for renewal of approval if it determines the applicant substantially meets the accreditation body requirements of this subpart.

(2) If SAMHSA determines that the applicant does not substantially meet the requirements set forth in this subpart. SAMHSA will notify the applicant of the deficiencies in the application and request that the applicant resolve such deficiencies within 90 days of receipt of the notice. If the deficiencies are resolved to the satisfaction of SAMHSA within the 90-day time period, the body will be approved as an accreditation body. If the deficiencies have not been resolved to the satisfaction of SAMHSA within the 90-day time period, the application for approval as an accreditation body will be denied.

(3) If SAMHSA does not reach a final decision on a renewal application before the expiration of an accreditation body's term of approval, the approval will be deemed extended until SAMHSA reaches a final decision, unless an accreditation body does not rectify deficiencies in the application within the specified time period, as required in paragraph (d)(2) of this section.

(e) Relinquishment of approval. An accreditation body that intends to relinquish its accreditation approval before expiration of the body's term of approval shall submit a letter of such intent to SAMHSA, at the address in paragraph (b) of this section, at least 9 months before relinquishing such approval.

(f) Notification. An accreditation body that does not apply for renewal of approval, or is denied such approval by SAMHSA, relinquishes its accreditation approval before expiration of its term of approval, or has its approval withdrawn, shall:

(1) Transfer copies of records and other related information as required by SAMHSA to a location, including another accreditation body, and according to a schedule approved by SAMHSA; and

(2) Notify, in a manner and time period approved by SAMHSA, all OTPs accredited or seeking accreditation by the body that the body will no longer have approval to provide accreditation services.

(g) Term of approval. An accreditation body's term of approval is for a period not to exceed 5 years.

(h) State accreditation bodies. State governmental entities, including political subdivisions thereof, may establish organizational units that may act as accreditation bodies, provided such units meet the requirements of this section, are approved by SAMHSA under this section, and have taken appropriate measures to prevent actual or apparent conflicts of interest, including cases in which State or Federal funds are used to support opioid treatment services.

Sec. 8.4 Accreditation body responsibilities.

(a) Accreditation surveys and for cause inspections.

(1) Accreditation bodies shall conduct routine accreditation surveys for initial, renewal, and continued accreditation of each OTP at least every 3 years.

(2) Accreditation bodies must agree to conduct for-cause inspections upon the request of SAMHSA.

(3) Accreditation decisions shall be fully consistent with the policies and procedures submitted as part of the approved accreditation body application.

(b) Response to noncompliant programs.

(1) If an accreditation body receives or discovers information that suggests that an OTP is not meeting Federal opioid treatment standards, or if survey of the OTP by the accreditation body otherwise demonstrates one or more deficiencies in the OTP, the accreditation body shall as appropriate either require and monitor corrective action or shall suspend or revoke accreditation of the OTP, as appropriate based on the significance of the deficiencies.

(i) Accreditation bodies shall either not accredit or shall revoke the accreditation of any OTP that substantially fails to meet the Federal opioid treatment standards.

(ii) Accreditation bodies shall notify SAMHSA as soon as possible but in no case longer than 48 hours after becoming aware of any practice or condition in an OTP that may pose a serious risk to public health or safety or patient care.

(iii) If an accreditation body determines that an OTP is substantially meeting the Federal opioid treatment standards, but is not meeting one or more accreditation elements, the accreditation body shall determine the necessary corrective measures to be taken by the OTP, establish a schedule for implementation of such measures, and notify the OTP in writing that it must implement such measures within the specified schedule in order to ensure continued accreditation. The accreditation body shall verify that the necessary steps are taken by the OTP within the schedule specified and that all accreditation elements are being substantially met or will be substantially met.

(2) Nothing in this part shall prevent accreditation bodies from granting accreditation, contingent on promised programmatic or performance changes, to OTPs with less substantial violations. Such accreditation shall not exceed 12 months. OTPs that have been granted such accreditation must have their accreditation revoked if they fail to make changes to receive unconditional accreditation upon resurvey or reinspection.

(c) Recordkeeping.

(1) Accreditation bodies shall maintain records of their accreditation activities for at least 5 years from the creation of the record. Such records must contain sufficient detail to support each accreditation decision made by the accreditation body.

(2) Accreditation bodies shall establish procedures to protect confidential information collected or received in their role as accreditation bodies that are consistent with, and that are designed to ensure compliance with, all Federal and State laws, including 42 CFR part 2.

(i) Information collected or received for the purpose of carrying out accreditation body responsibilities shall not be used for any other purpose or disclosed, other than to SAMHSA or its duly designated representatives, unless otherwise required by law or with the consent of the OTP.

(ii) Nonpublic information that SAMHSA shares with the accreditation body concerning an OTP shall not be further disclosed except with the written permission of SAMHSA.

(d) Reporting.

(1) Accreditation bodies shall provide to SAMHSA any documents and information requested by SAMHSA within 5 days of receipt of the request.

(2) Accreditation bodies shall make a summary of the results of each accreditation survey available to SAMHSA upon request. Such summaries shall contain sufficient detail to justify the accreditation action taken.

(3) Accreditation bodies shall provide SAMHSA upon request a list of each OTP surveyed and the identity of all individuals involved in the conduct and reporting of survey results.

(4) Accreditation bodies shall submit to SAMHSA the name of each OTP for which the accreditation body accredits conditionally, denies, suspends, or revokes accreditation, and the basis for the action, within 48 hours of the action.

(5) Notwithstanding any reports made to SAMHSA under paragraphs (d)(1) through (d)(4) of this section, each accreditation body shall submit to SAMHSA semiannually, on January 15 and July 15 of each calendar year, a report consisting of a summary of the results of each accreditation survey conducted in the past year. The summary shall contain sufficient detail to justify each accreditation action taken.

(6) All reporting requirements listed in this section shall be provided to SAMHSA at the address specified in Sec. 8.3(b).

(e) Complaint response. Accreditation bodies shall have policies and procedures to respond to complaints from SAMHSA, patients, facility staff, and others, within a reasonable period of time but not more than 5 days of the receipt of the complaint. Accreditation bodies shall also agree to notify SAMHSA within 48 hours of receipt of a complaint and keep SAMHSA informed of all aspects of the response to the complaint.

(f) Modifications of accreditation elements. Accreditation bodies shall obtain SAMHSA's authorization prior to making any substantive (i.e., noneditorial) change in accreditation elements.

(g) Conflicts of interest. The accreditation body shall maintain and apply policies and procedures that SAMHSA has approved in accordance with Sec. 8.3 to reduce the possibility of actual conflict of interest, or the appearance of a conflict of interest, on the part of individuals who act on behalf of the accreditation body. Individuals who participate in accreditation surveys or otherwise participate in the accreditation decision or an appeal of the accreditation decision, as well as their spouses and minor children, shall not have a financial interest in the OTP that is the subject of the accreditation survey or decision.

(h) Accreditation teams.

(1) An accreditation body survey team shall consist of healthcare professionals with expertise in drug abuse treatment and, in particular, opioid treatment. The accreditation body shall consider factors such as the size of the OTP, the anticipated number of problems, and the OTP's accreditation history, in determining the composition of the team. At a minimum, survey teams shall consist of at least two healthcare professionals whose combined expertise includes:

(i) The dispensing and administration of drugs subject to control under the Controlled Substances Act (21 U.S.C. 801 et seq.);

(ii) Medical issues relating to the dosing and administration of opioid agonist treatment medications for the treatment of opioid addiction;

(iii) Psychosocial counseling of individuals undergoing opioid treatment; and

(iv) Organizational and administrative issues associated with opioid treatment programs.

(2) Members of the accreditation team must be able to recuse themselves at any time from any survey in which either they or the OTP believes there is an actual conflict of interest or the appearance of a conflict of interest.

(i) Accreditation fees. Fees charged to OTPs for accreditation shall be reasonable. SAMHSA generally will find fees to be reasonable if the fees are limited to recovering costs to the accreditation body, including overhead incurred. Accreditation body activities that are not related to accreditation functions are not recoverable through fees established for accreditation.

(1) The accreditation body shall make public its fee structure, including those factors, if any, contributing to variations in fees for different OTPs.

(2) At SAMHSA's request, accreditation bodies shall provide to SAMHSA financial records or other materials, in a manner specified by SAMHSA, to assist in assessing the reasonableness of accreditation body fees.

Sec. 8.5 Periodic evaluation of accreditation bodies.

SAMHSA will evaluate periodically the performance of accreditation bodies primarily by inspecting a selected sample of the OTPs accredited by the accrediting body and by evaluating the accreditation body's reports of surveys conducted, to determine whether the OTPs surveyed and accredited by the accreditation body are in compliance with the Federal opioid treatment standards. The evaluation will include a determination of whether there are major deficiencies in the accreditation body's performance that, if not corrected, would warrant withdrawal of the approval of the accreditation body under Sec. 8.6.

Sec. 8.6 Withdrawal of approval of accreditation bodies.

If SAMHSA determines that an accreditation body is not in substantial compliance with this subpart, SAMHSA shall take appropriate action as follows:

(a) Major deficiencies. If SAMHSA determines that the accreditation body has a major deficiency, such as commission of fraud, material false statement, failure to perform a major accreditation function satisfactorily, or significant noncompliance with the requirements of this subpart, SAMHSA shall withdraw approval of that accreditation body.

(1) In the event of a major deficiency, SAMHSA shall notify the accreditation body of the agency's action and the grounds on which the approval was withdrawn.

(2) An accreditation body that has lost its approval shall notify each OTP that has been accredited or is seeking accreditation that the accreditation body's approval has been withdrawn. Such notification shall be made within a time period and in a manner approved by SAMHSA.

(b) Minor deficiencies. If SAMHSA determines that the accreditation body has minor deficiencies in the performance of an accreditation function, that are less serious or more limited than the types of deficiencies described in paragraph (a) of this section, SAMHSA will notify the body that it has 90 days to submit to SAMHSA a plan of corrective action. The plan must include a summary of corrective actions and a schedule for their implementation. SAMHSA may place the body on probationary status for a period of time determined by SAMHSA, or may withdraw approval of the body if corrective action is not taken.

(1) If SAMHSA places an accreditation body on probationary status, the body shall notify all OTPs that have been accredited, or that are seeking accreditation, of the accreditation body's probationary status within a time period and in a manner approved by SAMHSA.

(2) Probationary status will remain in effect until such time as the body can demonstrate to the satisfaction of SAMHSA that it has successfully implemented or is implementing the corrective action plan within the established schedule, and the corrective actions taken have substantially eliminated all identified problems.

(3) If SAMHSA determines that an accreditation body that has been placed on probationary status is not implementing corrective actions satisfactorily or within the established schedule, SAMHSA may withdraw approval of the accreditation body. The accreditation body shall notify all OTPs that have been accredited, or are seeking accreditation, of the accreditation body's loss of SAMHSA approval within a time period and in a manner approved by SAMHSA.

(c) Reapplication.

(1) An accreditation body that has had its approval withdrawn may submit a new application for approval if the body can provide information to SAMHSA to establish that the problems that were grounds for withdrawal of approval have been resolved.

(2) If SAMHSA determines that the new application demonstrates that the body satisfactorily has addressed the causes of its previous unacceptable performance, SAMHSA may reinstate approval of the accreditation body.

(3) SAMHSA may request additional information or establish additional conditions that must be met before SAMHSA approves the reapplication.

(4) SAMHSA may refuse to accept an application from a former accreditation body whose approval was withdrawn because of fraud, material false statement, or willful disregard of public health.

(d) Hearings. An opportunity to challenge an adverse action taken regarding withdrawal of approval of an accreditation body shall be addressed through the relevant procedures set forth in subpart C of this part, except that the procedures in Sec. 8.28 for expedited review of an immediate suspension would not apply to an accreditation body that has been notified under paragraph (a) or (b) of this section of the withdrawal of its approval.